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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/803,319

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Daniel G. Anderson

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(MIT-9128)

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10/28/2002

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EXAMINER

BAKER, MAURIE GARCIA

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 10/28/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary

Application No.
09/803,319

Applicant(s)
Anderson et al

Examiner
Mauri G. Baker, Ph.D.

Art Unit
1639



-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 18, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above, claim(s) 7, 13, and 21-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-12, and 14-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 6) ☐ Other: _____

DETAILED ACTION

Please note: The number of Art Unit 1627 has been changed to 1639. Please direct all correspondence for this case to Art Unit **1639**.

1. The Response filed July 18, 2002 (Paper No. 13) is acknowledged. No claims were cancelled, added or amended in this response. Therefore, claims 1-54 are pending.

Election/Restriction

2. Applicant's election of Group I (claims 1-20) and election of species is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 7 and 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Furthermore, claims 21-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Election was made without traverse in Paper No. 13.

4. Therefore, claims 1-6, 8-12 and 14-20 are under examination.

5. Also, please note MPEP § 803.02 with respect to species elections (emphasis added):

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. ***The prior art search, however, will not be extended unnecessarily to cover all nonelected species.*** Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-6, 8-12 and 14-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. Applicant's claims are directed to a "microarray of polymeric biomaterials". The claimed microarray also comprises "a base comprising a

cytophobic surface” and “a plurality of discrete polymeric biomaterial elements”. The claims use generic terminology such as “polymeric biomaterials”, “base” and “cytophobic surface”. These terms could encompass an enormous variety of different entities.

The language of the specification should describe the claimed invention so that one skilled in the art can recognize what is claimed. A description of a compound in terms of its function fails to distinguish the compound from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997⁴ Decided July 22, 1997; No. 96-1175).

The specification discloses only extremely limited examples of the preparation and use of such a “microarray”. These products are made up of pieces (i.e. “polymeric biomaterials”, “base” and “cytophobic surface”) that could encompass very different moieties such as various inorganic and organic molecules. Applicant’s claimed scope represents only an invitation to experiment regarding possible “polymeric biomaterials”, “base” materials and “cytophobic surface[s]”. The disclosure is neither representative of the claimed genus, nor does it represent a substantial portion of the claimed genus. Moreover, the claimed genus encompasses members which are yet to be prepared or

envisioned. This further evidences that instant disclosure does not constitute support for the claimed genus or a substantial portion thereof.

8. Claims 12 and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. These factors include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the level of one of ordinary skill;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and
- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The breadth of the claims and the nature of the invention: Claims 12 and 14 are drawn to a microarray where “at least one of said polymeric biomaterial elements further comprises a compound”. This represents very broad scope as the possible “compounds” are set forth in a very broad Markush listing. The invention is such that each of the components must be present in operable form for successful practice of the invention.

For example, the “compound” of claims 12 and 14 must be able to be bound to the microarray (in a non-covalent fashion; e.g. claim 14). The state of the prior art and the level of predictability in the art: While microarrays reading on those of the claims were well known in the art at the time of filing (see art rejection over Schreiber et al below), the specification gives no guidance to permit one of skill in the art to devise strategies for binding any “compound” to a microarray of polymeric biomaterial elements. The structures of possible variants are sufficiently diverse as to require further research as to how to make and use such microarrays. Moreover, one of ordinary skill would not know, *a priori*, how such a system should be configured from the components set forth in the instant claim. The level of one of ordinary skill: The level of skill would be high, most likely at the Ph.D. level. Such persons of ordinary skill in this art, given its unpredictability, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed. The amount of direction provided by the inventor and the existence of working examples: Applicants have not provided *any* examples of a microarray of polymeric biomaterial elements where “at least one of said polymeric biomaterial elements further comprises a compound”. Thus, further research would be necessary to make or use such a system as the practice of such would not be predictable. The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in making and using the claimed microarrays. Note that

there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites “drugs”, “growth factors”, “combinatorial compounds” and “adducts thereof, and mixtures thereof” in the Markush group. It is unclear what would or would not comprise each of the above members or “adducts thereof, and mixtures thereof”. The specification does not provide a standard for ascertaining such terms, and thus one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-6, 8-11 and 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Schreiber et al (WO 98/16830).

Schreiber et al disclose arrays of “droplets” on a surface (see Abstract and pages 5-6). The surface of Schreiber et al reads on the claimed “base” and the droplets can be associated with the surface via non-covalent interactions (see page 6, lines 13-14), reading on claims 8 and 9. Glass surfaces are disclosed by the reference, as well as other surfaces (see page 6, line 31). Polymer membranes reading on the claimed “hydrogels” (i.e. instant claims 4-6) are also disclosed by Schreiber et al. See page 10, lines 1-2 and surface described in Example 7. As these elements read directly on the “hydrogels” claimed, the surface is assumed to inherently have the claimed “cytophobic” properties. The reference discloses a wide variety of libraries of compounds that are contained in the “droplets”, see page 12, line 19 through page 14, line 29. As synthetic peptide libraries are described, this reads on the limitations of claims 10 and 11 (i.e. synthetic poly(amino acids)).

Finally, the droplet size (reading on "polymeric biomaterial elements"), density and arrangement of the arrays of Schreiber et al read directly on that claimed in the instant claims 15-20. See, for example, page 9, line 20 through page 12, line 17 and especially Figure 28 of the reference.


Status of Claims/Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
October 16, 2002



MAURIE GARCIA BAKER, Ph.D.
PATENT EXAMINER